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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/423,545	11/12/1999	KENJI SHIBATA	2139.15	6874

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EXAMINER

GUPTA, ANISH

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 10/18/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/423,545	SHIBATA ET AL.
	Examiner	Art Unit
	Anish Gupta	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 17 June 2002.

2a) This action is FINAL.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) 4-14 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-3, 15-16 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

## DETAILED ACTION

### *Election/Restriction*

1. Applicant's election of the species of Compound 23, SEQ ID NO. 31 in Paper No. 12 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

A search was conducted for the elected species of SEQ ID. NO. 31 and then extended to SEQ. 5 in the previous office action. In light of the amendment, the sequence search was again extended to SEQ ID NO. 1-4, 6-7, 16-30 and 32. No prior art was found on the elected species and, in accordance with the MPEP, the search of the Markush - type claim was be extended. Prior art was found that anticipates or renders obvious the Markush - type claim. The Markush - type claim is rejected and claims to the non - elected species held withdrawn from further consideration. Thus, claims 4-14 are withdrawn from consideration as corresponding to a non elected species.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-3 and 15-16 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Note, to further prosecution, even though claims 4-14 are withdrawn, this rejection is pertinent to those claims.

The claims still make references to residues  $X^p$  and  $X^q$ . However, there is no antecedent basis for these variables in the formula. It is unclear where such residues occur within formula (I) and how these variables affect the structure of the formula.

In their response, Applicants indicated that the claims specify  $X^p$  is selected from group X1 to X11 and residue  $X^q$  is selected from group X8 to X17 where  $q > p$ . However, no such citation appears in the claim. Note that the claim only talks about that functional group residue in  $X^p$  and a functional group residue in  $X^q$  together form a cyclic structure.

The rejection is maintained.

#### New Grounds For Rejection under 112 Second Paragraph

The claims have been amended to recite that "X1 to X17 may be deleted, substituted or added, or 12-aminododecanoic acid residues may be substituted or added." It is unclear where these residues are to be added. That is, are they to be added as qualifying as a X1 to X17 residue? If not, then do these aminododecanoic acid residues added to the C-terminal, N-terminal or side chain of the peptide. Further, how many residues are added or substituted to the peptide? Clarification is requested.

#### *Claim Rejections - 35 USC § 102*

4. The rejection of claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Halazonetis et al. It is hereby withdrawn.

***Claim Rejections - 35 USC § 103***

5. The rejection of claims 1-2, 6, 8, 15 and 16 rejected under 35 U.S.C. 103(a) as being unpatentable over Lane in view of Halzonitis et al. is hereby withdrawn.

**New Grounds For Rejection**

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Kemp et al. The claims are drawn to a peptide of formula I wherein there are at least seven amino acids present as recited for the X variables within the claim.

The reference teaches the sequence cyclo(CGGC<sup>X1</sup>GGC<sup>X2</sup>GGCG<sup>X3</sup>GG) which reads on the claimed invention. The prior art peptide reads on the claimed invention when X1 is allowed to be cys, X2 is allowed to be gly, X3 is allowed to be gly, X4 is allowed to be Cys, X5 is allowed be Gly, X6 is allowed to be Gly, X7 is allowed to be Cys, X8 is allowed to be Gly, and X9 is allowed to be Gly. Although the reference does not teach the DNA-binding activity or P53 protein-dependent transcription activity, such a limitation is an intended use limitation. An intended use limitation and intended use or field of use for the invention generally will not limit the scope of a claim.

Moreover, where the claimed and prior art products are identical or substantially identical in structure or composition, a *prima facie* case of either anticipation or obviousness has been established. In re Best, 195 USPQ 430, 433 (CCPA 1977). “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” In re Spada, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, *supra*.

8. Claims 1-3 and 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Halzonetis et al.

The claims are drawn to a peptide of formula I wherein there are at least seven amino acids present as recited for the X variables within the claim.

Halzonetis et al. teach peptides that have the ability to activate DNA binding of P53 (see abstract and page 29). The reference discloses numerous fragments within the 361-383 residues of human p53. Note, that the peptide of Lane et al. fall within residues 361-383 of p53. Halzonetis et al. also state that the peptide can be cyclized with the expectation of still having activation activity (see page 10, section c). The reference states “[t]he amino acid sequence of the cyclic peptides may be identical to the sequences of the L-amino acid peptide described above, except the topology is circular, rather than linear.” (See page 10, section c). The sequence KGQSTSRHKKL (Seq ID # 6) and SKKGQSTSRHKKL (Seq ID #7) of the reference reads on the claims starting with X6 to variable X16 for Seq Id #6 and X4 to X16 for Seq ID #7. Note that cyclic analogs of these peptides would correspond to deletion analogs of Seq ID #4 of the instant application. Given the

disclosure of the reference, one could readily envisage the cyclic peptides of KGQSTSRHKKL (Seq ID # 6) and SKKGQSTSRHKKL (Seq ID #7). Accordingly, the reference anticipates the claimed invention.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Note that the claims were amended to narrow the scope of the claim by limiting the length of the sequence to be at least seven amino acids. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can normally be reached on (703)308-2923. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
Anish Gupta 4/11/02

  
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